

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION**

P **PRO-BISOPROLOL – 5**

P **PRO-BISOPROLOL – 10**

Bisoprolol Fumarate Tablets USP

Read this carefully before you start taking **PRO-BISOPROLOL** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **PRO-BISOPROLOL**.

What is PRO-BISOPROLOL used for?

PRO-BISOPROLOL (bisoprolol fumarate) is used to treat mild to medium high blood pressure. It can be used alone or with other drugs to control blood pressure.

How does PRO-BISOPROLOL work?

PRO-BISOPROLOL is a type of medicine called a beta-blocker. It works by decreasing the blood pressure and reducing how hard the heart has to work.

What are the ingredients in PRO-BISOPROLOL?

Medicinal ingredients: bisoprolol fumarate

Non-medicinal ingredients: crospovidone, hydroxypropyl cellulose, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose polyethylene glycol and titanium dioxide.

The 5 mg tablets also contain ferric oxide red.

PRO-BISOPROLOL comes in the following dosage forms:

Tablets: 5 mg (pink) and 10 mg (white).

Do not use PRO-BISOPROLOL if:

- you are allergic to bisoprolol fumarate or any of the non-medicinal ingredients found in PRO-BISOPROLOL.
- you are pregnant or plan to become pregnant, or if you are breast-feeding. You must stop breast-feeding before taking PRO-BISOPROLOL.
- you have one of the following heart problems: heart failure or any other heart condition.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PRO-BISOPROLOL. Talk about any health conditions or problems you may have, including if you:

- have a history of heart failure.
- have asthma, bronchitis, emphysema, or other lung diseases.
- heart, kidney or liver disease.
- diabetes. PRO-BISOPROLOL may hide some of the symptoms of diabetes.

- an overactive thyroid gland (hyperthyroidism). PRO-BISOPROLOL may hide the symptoms of an overactive thyroid.
- will have an anaesthetic for surgery.
- have a history of allergic type reactions or are allergic to a many allergens.
- have a condition called peripheral artery disease. This means that your arteries are more narrow and don't carry blood to your legs as easily. Taking PRO-BISOPROLOL may cause symptoms or make your symptoms worse.

Other warnings you should know about:

Heart Failure

Patients taking beta-blockers can develop heart failure. Your doctor will check you for signs and symptoms of heart failure while you are taking PRO-BISOPROLOL.

Stopping treatment with PRO-BISOPROLOL

You should keep taking PRO-BISOPROLOL until your doctor tells you to stop. Your doctor will tell you to slowly stop taking it over a two-week period if and when it is time for you to stop.

Rash

You may develop a skin rash while taking PRO-BISOPROLOL. Tell your doctor if your rash becomes severe.

Lowered heart rate

Your heart rate may lower while you are taking PRO-BISOPROLOL. If it gets too low, your dose may be reduced or your doctor may tell you to stop taking PRO-BISOPROLOL.

Allergic reactions

While you are taking PRO-BISOPROLOL:

- a severe allergy reaction may be harder to treat.
- you may be more likely to have a severe allergic reaction.

Blood Tests

Your doctor will order regular blood tests for you while you are taking PRO-BISOPROLOL. The blood tests will help monitor your blood cells, kidneys and liver.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines. The following may interact with PRO-BISOPROLOL:

- Other beta-blocking Agents
- Reserpine or guanethidine (heart medication)
- Clonidine (high blood pressure medication)
- Verapamil, diltiazem, disopyramide (high blood pressure and heart medication)
- Fingolimod (immunosuppressant drug)
- Rifampin (antibiotic): may cause PRO-BISOPROLOL to work less effectively because it causes bisoprolol to leave the body quicker
- Common cold remedies and nasal drops: may cause an increase in blood pressure

How to take PRO-BISOPROLOL:

- Take PRO-BISOPROLOL **exactly** as your healthcare professional tells you.
- Do not miss doses or take extra doses, unless your healthcare professional tells you. If you are not clear about the directions, ask your healthcare professional or pharmacist. You may take PRO-BISOPROLOL along with other medications to help control your blood pressure. Take these medications as prescribed.
- Take PRO-BISOPROLOL once daily and at about the same time every day.
- Take PRO-BISOPROLOL tablets whole. Do not chew or crush them.

Usual dose:

Your doctor will determine your dose. You will likely take 5 mg to 20 mg once a day.

Your healthcare professional will regularly monitor your condition. Your dose may change depending on how well PRO-BISOPROLOL is working.

Overdose:

If you think you have taken too much PRO-BISOPROLOL, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

- If you miss a dose of PRO-BISOPROLOL, take it as soon as you remember on the same day.
- Take your next dose at your usual time the next day.
- Do not take more than one dose of PRO-BISOPROLOL at the same time to make up for a missed dose.

What are possible side effects from using PRO-BISOPROLOL?

These are not all the possible side effects you may feel when taking PRO-BISOPROLOL. If you experience any side effects not listed here, contact your healthcare professional. The most common side effects are:

- headache
- fatigue
- inflammation in the nose (rhinitis or sinusitis)
- diarrhea
- dizziness
- joint pain
- trouble sleeping
- nausea (feeling like vomiting)
- sore throat
- abdominal pain, indigestion
- back pain
- coughing

Tell your healthcare professional if:

- any of the side effects are serious or severe.
- you have any of the side effects for several days.

Medicines affect different people in different ways. Just because side effects have occurred in other patients does not mean you will get them. Discuss how you feel on PRO-BISOPROLOL with your healthcare professional or pharmacist. **Do not stop or restart PRO-BISOPROLOL on your own.**

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Aching muscles	√		
Allergic Reactions: dizziness or trouble breathing, hot or itching skin, rashes, swelling.			√
Bronchitis: cough, production of mucus, fatigue, shortness of breath, chest discomfort, slight fever	√		
Chest pain		√	
Depression		√	
Diarrhea	√		
Difficulty breathing: shortness of breath, stuffy nose, wheezing	√		
Dizziness	√		
Fatigue	√		
Fever	√		
Generalized body swelling		√	
Hot flushes	√		
Impotence (in men): trouble getting or keeping an erection		√	
Joint pain		√	
Muscle cramps	√		

Nerve pain: stabbing or burning pain		√	
Persistent noise in the ears	√		
Swelling of hands, ankles or feet		√	
Vision abnormality		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects
 You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect](#);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
 Health Canada, Postal Locator 1908C
 Ottawa, ON
 K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store at room temperature 15°C-30°C.
- Keep out of sight and reach of children.

If you want more information about PRO-BISOPROLOL:

This document plus the full product monograph, prepared for health professionals can be found by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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